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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,274	09/24/2001	Jaap Van Der Louw	99469 US	2129

7590

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EXAMINER

QAZI, SABIHA NAIM

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 07/02/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/937,274

Applicant(s)

VAN DER LOUW ET AL.

Examiner

Sabiha Naim Qazi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 17 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 13-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1 and 3-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

Art Unit: 1616

### DETAILED ACTION

Claims 1, 3-11 and 13-16 are pending.

Claims 1, 3-11 are examined, 13-16 are withdrawn from consideration as non elected invention.

No claim is allowed.

Response filed in paper no. 6 is hereby acknowledged. Argument are found persuasive and acceptance of error in RN of BE 623844 is received from Chemical Abstract service therefore, 102 rejection is withdrawn. Claims 1, 3-11 stand rejected under 35 U.S.C. 103(a) as being unpatentable over GB 129897 is maintained for the same reasons as set forth in our previous office action. Arguments were fully considered but are not found persuasive because claims are generically taught by the prior art of record. The difference in being an alpha isomer of a prior art compound having a beta configuration is not considered patentably distinct criteria in absence of showing unexpected results. An isomer is considered obvious over the other isomer of the same compound. At the time of invention it would have been obvious to select any isomer of the compound taught by the prior art because such structurally similar compounds suggest one another and would be expected to share common properties.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

#### **Graham Factual Inquiries (MPEP 2141, 2144.08)**

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 3-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solo et al. (Steroids, Vol. 40, No. 6, pp603-614).

**1. Determining the scope and contents of the prior art (MPEP 2141.01).**

Solo teaches steroidal compounds which embraces applicant's claimed compounds. See the entire documents especially compounds 3, 4 and 5 on page 604, where X is OH, Y is H and R is ethyl, nPr and nBu respectively. These compounds are taught to be useful as androgen and as aromatase inhibitors.

**2. Ascertaining the differences between the prior art and the claims at issue (MPEP 2141.02).**

Instant claims differ from the reference in claiming 19-nor 7-alkyl and 17 OH substituted steroid. The prior art of record is drawn to structurally similar compounds which differ from the compounds embraced by the instant claims in that they are homolog. Instant claims differ from the reference in having no methyl group at 19 position of the steroid ring, other substituents are taught by the prior art.

**3. Resolving the level of ordinary skill in the pertinent art (MPEP 2141.03).**

Compounds that differ only by the presence of an extra methyl group are homologue. The skilled artisan would have been motivated to prepare additional beneficial steroidal compounds with one less methyl group at 19 position, because it is recognized in the art that homolog are structurally similar and would be expected to possess similar properties. . See *Ex parte Henze* (POBA 1948) 83 USPQ 167 .

**4. Considering objective evidence present in the application indicating obviousness or nonobviousness (MPEP 2142, 2143, 2143.01, 2143.02, 2144.04 and 2144.09).**

Compounds that differ only by the presence of an extra methyl group are homologue. Homologue are of such close structural similarity that the disclosure of a compound renders prima facie obvious its homologue

The homologue is expected to be prepare able by the same method and to have the same properties i.e. useful an intermediate in the preparation of vitamin D. This expectation is then deemed the motivation for preparing homologue. Homologue are obvious even in the absence of a specific teaching to methylate, *In re Wood* 199 USPQ 137; *In re Hoke* 195 USPQ 148; *In re Lohr* 137 USPQ 548; *In re Magerlein* 202 USPQ 473; *In re Wiechert* 152 USPQ 249; *Ex parte Henkel* 130 USPQ 474; *In re Fauque* 121 USPQ 425; *In re Druay* 138 USPQ 39. In all of these cases, the close structural similarity of two compounds differing by only one (or two) methyl groups sufficed; no specific teaching to methylate was present or required.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

#### **Telephone Inquiry Contacts**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Naim Qazi whose telephone number is 703-305-3910. The examiner can normally be reached on First Friday Off.

Art Unit: 1616

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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June 29, 2002



SABIHA QAZI, PH.D  
PRIMARY EXAMINER